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August 18, 2009
Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
Ex parte Pope et al.
Appeal No. _____**

Serial No.: 10/700,738
Filed: November 4, 2003
Art Unit: 3767
Examiner: Elizabeth MacNeill
Appellants: Brian Pope and Zhan Liu
For: **SYRINGE PUMP RAPID OCCLUSION DETECTION SYSTEM**
Atty. Docket No.: MDX-297
Confirmation No.: 4966

Cincinnati, OH 45202

August 18, 2009

Mail Stop APPEAL BRIEF – PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

REPLY BRIEF

This Reply Brief under 37 C.F.R. §41.41(a)(1) is in response to the Examiner's Answer dated June 19, 2009 in the above-captioned appeal.

This Reply Brief is filed to focus on specific issues raised in the Examiner's Answer and issues related thereto so that the Board may have a more complete picture of Examiner's rejections and prosecution of this application.

I. ARGUMENT

A. Examiner's Answer

In the Answer, Examiner reiterates arguments presented in the Final Office Action, then seeks to recast the factual details of the art in order to, effectively, create new theories of support for the rejections. However, those new theories are of no aid to Examiner.

Examiner's allegations are that mean values and instantaneous values are interchangeable such that a period of time of Δt , an integral part of the teachings of Jhuboo, may be considered "irrelevant." As such, Examiner attempts to ignore key sections of the specification of Jhuboo to allege that it would be obvious to one of ordinary skill in the art to use instantaneous pressure values (e.g., a Δt of zero or approaching zero). Put simply, Examiner attempts to divorce Δt from Jhuboo because the effect of adjusting Δt to an instantaneous or near instantaneous value is fatal to the rejections. Thus, Examiner persists in ignoring parts of a reference that are fatal to the rejections, which is akin to misleading this tribunal. That is clearly unacceptable.

B. Examiner May Not Ignore Contrary Teachings of Jhuboo

Examiner cites to col. 1, ll. 15-30 of Jhuboo to note that "workers may choose to use either instant or mean forces depending on the sensitivity of the occlusion levels." Examiner is taking a willfully blind reading of that section of Jhuboo. In col. 1, ll. 15-30, Jhuboo merely describes prior art pressuring monitoring systems that read a pressure at discrete time intervals and trigger an alarm when the pressure exceeds a fixed level. Jhuboo goes on to note the inherent flaws in such occlusion detection, particularly occlusion detection by comparison of an instantaneous pressure to a pressure threshold. See col. 1, ll. 23-26. Therefore, a plain reading of Jhuboo shows that it explicitly teaches away from using instantaneous pressures.

Examiner thus mischaracterizes the prior art disclosed in Jhuboo to engage in the fiction that mean values and instantaneous values are interchangeable. Examiner feels that she is therefore free to ignore that Jhuboo actively teaches away from using instantaneous pressures. This is clear error. In evaluating obviousness, "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP §2141.02, *citing W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Moreover, "[i]t is impermissible to disregard portions of a prior art reference that teach away from an invention...." *Hughes Aircraft Co. v. U.S.*, 8 USPQ2d 1580, 1586 (Cl. Ct. 1988), *citing Akzo, N.V. v. United States Int'l Trade Comm'n*, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 2490 (1987); *W.L. Gore & Assoc.*, 221 USPQ at 311. Thus, Examiner cannot cherry-pick Jhuboo to take only that which is desired. Examiner must take the reference as a whole, including those parts that actively teach away from the proposed modification of Jhuboo.

1. Jhuboo Teaches Away from a Δt of Zero or Approaching Zero

For example, Jhuboo uses Δt to determine the time period during which to measure the average pressure. See FIG. 8, as well as col. 4, ll. 55-67. However, by adjusting Δt to zero or a value approaching zero, the value of a first average force will, necessarily, be the same as the value of a second average force. Thus, any calculation of the difference between the first average force and second average force (e.g., ΔP) will, in that scenario, also have to be zero, rendering any calculation of ΔP (as it used in determining a gradient constant, an occlusion, and other calculations) zero. The results is a non-functional system in which all values of a difference between two force values are zero. Additionally, Jhuboo uses Δt in the denominator to determine the value of the gradient constant. See FIG. 8, as well as col. 5, ll. 2-9. As such,

were Δt set to zero, or even a value approaching zero, the result would be a gradient of infinity, rendering the determination of a gradient constant useless. Thus, it is clear that Jhuboo teaches away from using a Δt of zero or one that approaches zero, as it would result in a non-functional system as well as render determinations of a gradient constant useless.

In regard to the perfusion rate, Jhuboo expresses an inverse dependency between Δt and the perfusion rate. *See* col. 5, ll. 40-52. However, inasmuch as Δt may be decreased, it must be done so in light of an exemplary value of one minute (col. 6, ll. 7-9). This is clearly neither instantaneous or near instantaneous. For example, the perfusion rate in Jhuboo is set by a user (*e.g.*, col. 5, ll. 54-55) with Δt having an inversely proportional relationship to that rate (*e.g.*, col. 5, ll. 53-54). When Δt is set to a value, such as 1 μ Sec (which is certainly still well above a value approaching zero), the perfusion rate escalates to a value of 1000 L per hour based on the calculations in col. 5, ll. 53-55. Correspondingly, for Δt to be set to a value of zero, the perfusion rate would seem to balloon incredibly to a value of infinity. That perfusion rate would undoubtedly cause harm to any patient.

In the Answer, Examiner rightly notes that Jhuboo discloses that "[i]f Δt is small, the system will be sensitive to rapid pressure increases." *See* col. 5, ll. 44-46. However, the adjustment of Δt is again in relation to its exemplary value of one minute, which is neither instantaneous nor near instantaneous. *See* col. 5, ll. 54-55 and col. 6, ll. 7-9. As discussed above, reducing Δt to a value of 1 μ Sec, which is still neither instantaneous nor near instantaneous, would have disastrous consequences. Thus, it is again clear that Jhuboo teaches away from using a Δt of zero or one that approaches zero as Jhuboo is not only constrained to an exemplary value of a Δt of one minute, but also that a Δt of zero or one that approaches zero would result in disastrous consequences for a patient.

In regard to determining occlusions, Jhuboo discloses that an occlusion is determined when $\Delta P \geq S_0 \Delta t$. *See* col. 5, ll. 10-39. As such, were Δt forced to zero or a value approaching zero, it is clear that the product of $S_0 \Delta t$ would always be forced to zero, resulting in ΔP always being greater than $S_0 \Delta t$. Thus, the system of Jhuboo would always determine that an occlusion has occurred, thus rendering occlusion detection completely inoperable.

Finally, Jhuboo discloses numerous methods of optimizing Δt . *See* FIG. 9 and FIG. 10, as well as col. 6, ll. 1-61. In particular, Jhuboo's optimization procedure establishes that Δt should never be set to approach or equal, as to do so would utterly destroy the purpose of that optimization. FIGS. 9 and 10 of Jhuboo both show a determination of whether $|P_{i+1} - P_i| > K_1 S_0 \Delta t_i$ (*e.g.*, calculations in col. 6). However, setting Δt to approach or equal zero prevents any optimization of Δt and destroys the illustrative procedure disclosed in FIGS. 9 and 10. Thus, Jhuboo again actively teaches away from using instantaneous or even near instantaneous force values, as Jhuboo relies upon Δt for optimization of its average force values.

In total, Δt is an integral part of Jhuboo that is used in a variety of ways for Jhuboo to operate for its intended purpose. Moreover, Jhuboo's use of Δt explicitly teaches away from utilizing instantaneous or near instantaneous force values, in which Δt would be zero or approach zero. Thus, despite Examiner's allegations to the contrary, it is amply demonstrated that Jhuboo would lead a person of ordinary skill in the art to follow a different path than setting Δt equal to or approaching zero, as otherwise the person of ordinary skill would be traversing a path to an inoperable system. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."); *see also McGinley v.*

Franklin Sports, Inc., 262 F.3d 1339, 1354, 60USPQ2d 1001, 1010 (a reference may teach away from a use when the use would render the result inoperable); *In re Gordon*, 733 F.3d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (a reference teaches away from proposed modifications that render the disclosed invention inoperable for its intended purpose). Even *KSR* indicates that when the prior art teaches away from a combination, that combination is more likely to be nonobvious. *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739-1740 (2007).

2. Δt is an Integral Part of Jhuboo that Cannot Be Summarily Dismissed as "Irrelevant"

Regarding the "irrelevancy" of Δt , the Examiner must take a reference in its entirety, especially when portions of the reference teach away from a claimed invention. Again, "[i]t is impermissible to disregard portions of a prior art reference that teach away from an invention...." *Hughes Aircraft*, 8 USPQ2d at 1586, citing *Akzo*, 1 USPQ2d at 1246; *W.L. Gore*, 220 USPQ at 311. But that is what Examiner does here. Under the rubric of obviousness, Examiner removes the parts of Jhuboo that are fatal to her rejections. To extricate Δt as proposed by Examiner is unlawful and amounts to nothing more than impermissible hindsight using information gleaned from Appellant's own patent application to force the teachings of Jhuboo into the rejections, which is fatal to rejection under 35 U.S.C. §103. MPEP §2145; *W.L. Gore*, 220 USPQ at 311. This is clear error and must be reversed.

C. Removing Δt Would Change the Principle Of Operation of Jhuboo and Fail to Yield a Predictable Result

Moreover, Examiner's proposed combination, in which Δt is eliminated altogether, would change the principle of operation of the prior art invention in Jhuboo and further fail to yield a predictable result. For example, removing Δt would reduce the equation for the value of the gradient constant to $S = \Delta P$ (see col. 5, l. 5), would reduce the equation for

determining an occlusion to $S_0 \leq \Delta P$ (*see* col. 5, ll. 17-30), and would completely eliminate the optimization described from col. 5, l. 40 to col. 6, l. 61, as well as FIGS. 9 and 10. Thus, Examiner's proposed combination in which Δt is "irrelevant" would result in the gradient constant and occlusion both being determined by the difference between a first force and a second force such that an occlusion is always determined (as S would always be equal to S_0 , which would always be equal to ΔP), while the optimization of the time period in which to determine average force values would be eliminated. This is a prime example in which the proposed combination changes the principle of operation of the prior art invention. As such, it is abundantly clear that the teachings of Jhuboo are not sufficient to render the claimed invention *prima facie* obvious. MPEP §2143.01; *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious).

Furthermore, the proposed combination fails to yield a predictable result. *KSR* held that a "predictable result" refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, Nos. 2008-1240, -1253, -1401, slip op. at 13 (Fed. Cir. June 1, 2009) *citing* *KSR*, 127 S. Ct. at 1739-40. This is not a case that fits the notion that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 127 S. Ct. at 1739. Nor is this a case that fits the maxim that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR*, 127 S. Ct. at

1740 (*quoting Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). Rather, in the present case, Examiner attempts to create a combination from the old elements of Jhuboo while ignoring Δt in an attempt to render the claimed invention obvious. However, it is clearly evident that to remove Δt results in Jhuboo failing to work for its intended purpose and further teaches away from the claimed invention. Why would a person of ordinary skill in the art work with Jhuboo to follow a design path that, for that reference, would lead into an inoperable combination? They would not. Indeed, nonobvious lies where a proposed combination would deter any investigation in such a combination. *See Depuy Spine*, slip op. at 14 ("The opposite conclusion [of obviousness] would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention."), *accord U.S. v. Adams*, 383 U.S. 39, 52 (1966) (upholding nonobviousness where references teaching away from the claimed combination would "deter any investigation into such a combination"). Thus, as the Federal Circuit made clear, "[a]n inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements." *Depuy Spine*, slip op. at 14. That is the case here.

D. Dependent Claims 3, 15, and 57

In the Answer, Examiner asserts that no definition of a "steady state" or "steady state condition" is given in the specification. Appellants disagree. In paragraph [0047], a "steady state" is defined to include "a status of the system 10 at which initial conditions of an infusion application will generally have less impact on occlusion determination processes." Moreover, a steady state condition is further described in paragraph [0065] as a time after which elevated startup slopes associated with a pre-steady state timeframe normally level off. Similarly, the American Heritage Dictionary, 4th edition (2009) defines "steady state" as "a stable

condition that does not change over time or in which change in one direction is continually balanced by change in another." Appellants thus submit that a "steady state" or "steady state condition" is defined in the specification and also a term of art to one of ordinary skill in the art.

However, Jhuboo still fails to determine a steady state condition. In rejecting claims 3, 15, and 57, each of which at least partially recite "determining a steady state condition," Examiner asserts that one of ordinary skill in the art would interpret that to include deducing or determining predetermined parameters. By doing so, Examiner ignores the limitation of "steady state" and merely reduces the subject dependent claims to "determining a parameter." This is clear error. As discussed above, a steady state is a condition in which elevated startup slopes normally level off. Thus, paragraphs [0069]-[0067], as well as FIG. 6, are directed toward determining a steady state. As such, it is clear that a steady state condition is a condition or status of a system and is not merely a "parameter" as alleged by the Examiner. However, it is completely false to suggest that the disclosure of Jhuboo related to determination of the gradient constant is relevant to determining a steady state condition. As discussed above, Jhuboo states that an occlusion may be detected if $\Delta P \geq S_0 \Delta t$. In particular, Jhuboo states that S_0 is a numeric value "deduced experimentally by measuring the gradients of the pressure/time curve with obstructions found in the fluid line and different flow rates." Col. 5, ll. 31-33. It is ludicrous for Examiner to assert that determining the value for a parameter, S_0 , is the same as determining a steady state condition of a live system without a more thorough explanation to which the Appellants can respond. In fact, "to conclude otherwise can only be the result of information gleaned from Appellant's own patent application," which is impermissible hindsight reconstruction and fatal to a 35 U.S.C. § 103 rejection. MPEP §2145; *W.L. Gore*, 721 F.2d.

Thus, for at least these further reasons, the rejections of dependent claims 3, 15, and 57 are clearly in error and must be reversed in any event.

II. CONCLUSION

It can hardly be said to be obvious to develop an infusion pump by modifying a reference in a manner that would cause it to fail to correctly determine occlusions, and certainly it cannot be said that ordinarily skilled artisans would consider that an acceptable result. Yet that is the upshot of the obviousness rejections here. Clearly, Examiner's arguments are flawed, and no *prima facie* case of obviousness has been established with regard to any of the claims.

For at least the reasons discussed above, and as set out in the Appeal Brief, Appellants respectfully submit that the rejections of claims 1-3, 5-36 and 46-80 are in error and should be reversed.

Respectfully submitted,
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